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Datasheet for the decision of 10 May 2017

Case Number: T 2287/11 - 3.3.08

Application Number: 04785150.6

Publication Number: 1664348

IPC: C12Q1/70

Language of the proceedings: EN

Title of invention:
DETECTION OF HPV

Applicant:
THIRD WAVE TECHNOLOGIES, INC.

Headword:
Detection of HPV/THIRD WAVE TECHNOLOGIES

Relevant legal provisions:
EPC Art. 83, 84, 111, 123(2)
RPBA Art. 13(3)

Keyword:
Main request and 1st to 3rd auxiliary request - admitted
Main request, 1st and 2nd auxiliary request - added matter (yes)
3rd auxiliary request - added matter (no)
Requirements of Articles 84 and 83 EPC - fulfilled
Remittal for further prosecution

Decisions cited:
G 0010/93, T 1944/10

Catchword:

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European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2287/11 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 10 May 2017

Appellant: (Applicant)	THIRD WAVE TECHNOLOGIES, INC. 502 South Rosa Road Madison, WI 53719 (US)
Representative:	Westphal, Dr Thomas Glawe, Delfs, Moll Partnerschaft mbB von Patent- und Rechtsanwälten Postfach 13 03 91 20103 Hamburg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 May 2011 refusing European patent application No. 04785150.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Julià
Members:	M. R. Vega Laso
	D. Rogers

Summary of Facts and Submissions

I. The appeal lies from a decision of an examining division posted on 27 May 2011 refusing the European patent application No. 04 785 150.6 under Article 97(2) EPC. The application with the title "Detection of HPV" was filed under the Patent Cooperation Treaty and published as WO 2005/030041 (in the following "the application as filed").

II. In the decision under appeal, the examining division found that the subject-matter of the sets of claims according to any of the main request and the first to fifth auxiliary requests then on file did not involve an inventive step within the meaning of Article 56 EPC. Additionally, as an *obiter dictum* the examining division observed that all requests then on file suffered from a deficiency with respect to Article 84 EPC.

III. Together with its statement of grounds of appeal, the appellant (applicant) filed a copy of the sets of claims underlying the decision under appeal, four additional sets of claims as sixth to ninth auxiliary requests, and new evidence. As a subsidiary request, the appellant requested oral proceedings.

IV. The board summoned the appellant to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board referred to decision G 10/93 of the Enlarged Board of Appeal (OJ EPO 1995, 172) and provided observations on issues under Articles 123(2), 84, 83, 54 and 56 EPC to be discussed at the oral proceedings.

V. Upon receipt of a reasoned request by the appellant, the oral proceedings were postponed.

VI. On 10 April 2017, the appellant replied to the board's communication and submitted three sets of amended claims as 1st to 3rd auxiliary requests which replaced the corresponding requests previously on file. The former 4th to 9th auxiliary requests were withdrawn.

VII. Oral proceedings were held on 10 May 2017. During the proceedings, the appellant filed a further set of claims as 4th auxiliary request. After withdrawing its main request, the appellant re-numbered the 1st to 4th auxiliary requests as main request and 1st to 3rd auxiliary request, respectively.

VIII. Independent claim 6 according to the **main request** reads as follows:

"6. A kit comprising oligonucleotide detection assay components for detecting HPV sequences, wherein said components consist of:

a) a first, second or third pool of oligonucleotide sets, said sets consisting of first and second oligonucleotides, wherein the combination of first and second oligonucleotides form an invasive cleavage structure in combination with a target sequence comprising a HPV sequence as indicated in the table below:

First pool

1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NO: 77	SEQ ID NO: 78	51
SEQ ID NO: 79	SEQ ID NO: 80	51
SEQ ID NO: 81	SEQ ID NO: 82	56
SEQ ID NO: 83	SEQ ID NO: 84	56
or		
1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NOS: 122, 123, 125	SEQ ID NOS: 124, 126	51, 56

Second pool

1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NO: 85	SEQ ID NO: 86, 87	18, 59
SEQ ID NO: 88	SEQ ID NO: 89, 90	45, 59
SEQ ID NO: 91	SEQ ID NO: 92, 93	18, 45
SEQ ID NO: 94	SEQ ID NO: 95, 96	39, 68, 70
SEQ ID NO: 97	SEQ ID NO: 98, 99, 100	39, 68, 70
or		
1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NOS: 127, 130, 131, 132, 134, 138, 139, 142, 143, 146, 147, 148, 154, 157	SEQ ID NOS: 128, 129, 133, 135, 136, 137, 140, 141, 144, 145, 149, 150, 151, 152, 153, 155, 156, 158, 159	18, 39, 45, 59, 68, 70

Third pool

1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NO: 101	SEQ ID NO: 102, 103, 104	33, 52, 58, 67
SEQ ID NO: 105	SEQ ID NO: 106, 107	31, 35
SEQ ID NO: 108	SEQ ID NO: 109	33, 52, 58, 67
SEQ ID NO: 110	SEQ ID NO: 111, 112, 113	16, 31, 35
SEQ ID NO: 114	SEQ ID NO: 115, 116	16, 31
or		
1st oligonucleotides	2nd oligonucleotides	Target sequences comprising HPV type
SEQ ID NOS: 160, 163, 167, 170, 173, 177, 180, 182, 185, 188, 191	SEQ ID NOS: 161, 162, 164, 165, 166, 168, 169, 171, 172, 174, 175, 176, 178, 179, 181, 183, 184, 186, 187,189, 190, 192, 193	16, 31, 33, 35, 52, 58, 67

b) a FEN endonuclease;

c) an internal control;

d) a plurality of fluorescence resonance energy transfer (FRET) cassettes configured to generate a detectable signal in a FRET assay in response to a cleavage of the first oligonucleotide in said invasive cleavage structure; and

e) assay reagents comprising a buffer solution."

Claims 1 to 5 relate to methods for detecting the presence or absence of multiple HPV target nucleic acids in a sample.

IX. The **1st and 2nd auxiliary requests** have an identical claim 1 which reads:

"1. A method for detecting the presence or absence of multiple HPV target nucleic acids in a sample, wherein said HPV nucleic acids are from two or more strains in a set of strains of HPV, said method comprising:

a) treating said sample with a pool of probe sets in a single reaction, wherein each of said probe sets comprises a first oligonucleotide and second oligonucleotide configured to form an invasive cleavage structure with said target nucleic acid, wherein

i) each of said probe sets comprises probe sets configured to form an invasive cleavage structure with target nucleic acid from at least two different strains of HPV in said set of strains of HPV, and

ii) for each different strain of HPV in said set of strains of HPV, at least two of said probe sets are configured to hybridize to at least two different regions of an HPV target nucleic acid to form an invasive cleavage structure with target nucleic acid from the strain;

under conditions wherein said probe sets will form invasive cleavage structures if target nucleic acid is present;

b) determining the presence or absence of formation of at least one invasive cleavage structure in said sample in an invasive cleavage assay configured to detect at least one HPV nucleic acid and exposing the sample to the detection assay under conditions such that at least one HPV nucleic acid can be detected, thereby detecting the presence or absence of HPV nucleic acids from at least one strain from said set of strains of HPV in said sample,

and wherein said pool of probe sets is selected from the group of pool sets as indicated in the table below:

[Table listing a first, second and third pool of probe sets as included in claim 6 of the main request, see section VIII above]"

In the 1st and 2nd auxiliary requests, dependent claims 2 and 4 of the main request have been deleted and the remaining claims re-numbered. In the 2nd auxiliary request, claim 6 of the main request has also been deleted.

X. The **3rd auxiliary request** consists of three claims. Claim 1 differs from the corresponding claim of the 1st and 2nd auxiliary requests (see section IX above) in that:

- in step a) i) the wording "*each of said probe sets comprises ...*" has been replaced by "***said pool*** *of probe sets comprises ...*" (emphasis added by the board);

- in step a) ii) the wording "*... at least two different regions of an HPV target nucleic*

acid ..." has been amended to read "*... at least two different regions of* ***each*** *HPV target nucleic acid ...*" (emphasis added by the board);

- in step b) the following wording has been inserted: "[... can be detected] *wherein a fluorescence resonance energy transfer (FRET) cassette configured to generate a detectable signal in a FRET assay in response to a cleavage of the first oligonucleotide in said invasive cleavage structure is used* [thereby detecting ...]"; and

- at the end of the claim the following wording has been inserted and the table has been replaced by a new table as follows:

"[...] *and wherein the 1st oligonucleotide is indicated as Probe and the second oligonucleotide is indicated as Invader*

	Assay Name	Strains Detected by Assay	Gene	Oligo Type	Sequence (5'-3')
	A5/A6 Pool				
SEQ ID NO: 77	W13	51	E7	Probe	GGCAGTCTGGGAGTGTACAGCAGATGTTTATGGGC
SEQ ID NO: 78				Invader	AGATGGCGACACCAATCCGGGCAGAGGAGACACCCTTCGCGTTC
SEQ ID NO: 79	W17	51	L1	Probe	GGCAGTCTGGGAGTGCTTAGCCTGTGGAAGGG
SEQ ID NO: 80				Invader	CGTTCCTTTAGATCTACATTCCAAAATTTATATTTGGCCAAAGGATCTGC
SEQ ID NO: 81	O5	56	LCR	Probe	GGCAGTCTGGGAGTGCAGCTTATTCTGAGTGGACT
SEQ ID NO: 82				Invader	ACCGAAACGGGTTTATGACCGAAAACGGTACATATAAAAGC
SEQ ID NO: 83	O12	56	L1	Probe	GGCAGTCTGGGAGTGTTGGTGGCTGTTACCG
SEQ ID NO: 84				Invader	GCTCCAACGGGTTTCCTGCCATCCCACAATTTATATTTAGCTAATGGGTCCTGTTTTTCTC
	A7 Pool				
SEQ ID NO: 85	T3	18,59	E6	Probe	CGCGCCGAGGGATCCTCAAAGCGAGCC
SEQ ID NO: 86				Invader	ATTCTGTGCACAAATCAGGTAGCTTGTAGGGTCGTCGTGTTGC
SEQ ID NO: 87				Invader	TGCACAAATCAGGCAGTTTGTAAGGTCGTTGTGTAGC
SEQ ID NO: 88	R4	45,59	E7	Probe	CGCGCCGAGGGAGCGGAACCACAGCGT
SEQ ID NO: 89				Invader	GGGCCATAAATAATAATTATCCTCATGCACAACTACCGGCCCGACC
SEQ ID NO: 90				Invader	GAGGAAGAAAACGATGAACTAGATGGAGTTAATCATCATTTGCTACTAGCTAGACC
SEQ ID NO: 91	F11	18,45	L1	Probe	CGCGCCGAGGGATTGGACAAAACGATATGTATCCA
SEQ ID NO: 92				Invader	GGTGTAGCATCCTTTTGACAGGTAATAGCAACAT
SEQ ID NO: 93				Invader	GGTGTAGTATCCTTTTGACAGGTAACAGCAACTT
SEQ ID NO: 94	K15	39,68,70	E6	Probe	CGCGCCGAGGAGGAAGCTTTACAGGACAGTG
SEQ ID NO: 95				Invader	CTGAAACCGTTGAGTCCAGCAGAAAAATTAAGGCACCTAACTACCAAACGAAGATTTCATAAAATAGCC
SEQ ID NO: 96				Invader	CTGAAACCGTTGTGTCCAGCAGAAAAATTAAGACACGTTAATACCAAACGAAGATTTCATCAAATAGCC
SEQ ID NO: 97	K5	39, 68, 70	E6	Probe	CGCGCCGAGGGGTCCGGCAATTTGTATGGC
SEQ ID NO: 98				Invader	GTCTTGCAAGGTAGTGTCCAGCGCTGTGCACAC
SEQ ID NO: 99				Invader	GTAATGTCATGCAATGTGGTGTCCAACGTCGTGCACAC
SEQ ID NO: 100				Invader	TGTCTTGCAAGGTAGTGTCCAGCGTCGTGCACAC
	A9 Pool				
SEQ ID NO: 101	J4	33,52,58,67	E7	Probe	CGCGCCGAGGGTCCATCTGGCCAGTCCA
SEQ ID NO: 102				Invader	CCCAAATATAATCACAATGCTGATGTAGTAATTGCTTATGGCTTGTTCTGCTTC
SEQ ID NO: 103				Invader	TGTAGTAATTAGCTGTGGCAGGTTGTGCTTC
SEQ ID NO: 104				Invader	GCTCCAACGGGTTTCCTGCAGTAACAATTTGGTAATTGGTTGTATCTGGTTTTGCTTC
SEQ ID NO: 105	N12	31,35	L1	Probe	CGCGCCGAGGGCACGTTGCAGCCAATATG
SEQ ID NO: 106				Invader	CAGCCAAGCGCAGGCGCCCAACAAATAGCATTATTGTGTCCCTGAC
SEQ ID NO: 107		35, 1A		Invader	CAGCCAAGCGCAGGCGGTTACTCCAACAAATAGCATTATTATGGCCTTGTC
SEQ ID NO: 108	Z1	33,52,58,67	L1	Probe	CGCGCCGAGGGCCACGGTGTACCTGCCT
SEQ ID NO: 109				Invader	ATGTCCGTGAGGCGGCCTAGTGAGC
SEQ ID NO: 110	AN1	16, 31, 35	E7	Probe	CGCGCCGAGGGGTTATGCTTGTCCAGCTG
SEQ ID NO: 111				Invader	CAGCCAAGCGCAGGCGCATTTCCAACAGGACGTTACAATATTATAATTGGAGGTGTCTC
SEQ ID NO: 112				Invader	CAGCCAAGCGCAGGCGCTGACAACAACAGGTAACGATATTGTAATTGGATGTGTCCC
SEQ ID NO: 113				Invader	CAGCCAAGCGCAGGCGGCAACACAAGGTTACAATATTGTAATGGGCTCTGTCCC
SEQ ID NO: 114	A3a	16,31	L1	Probe	CGCGCCGAGGACATAATCATCCGTGCTTACAAC
SEQ ID NO: 115				Invader	TGCCTGCATGATAATAGATGTTTGTGCGTGCAT
SEQ ID NO: 116				Invader	GCCTAGAACTGCCTGCGTGATAGTATATGTTTGTTCGTGTTT

or

	Assay Name	Strains Detected by Assay	Gene	Oligo Type	Sequence (5'-3')
	A5/A6 Pool				
SEQ ID NO: 122	W18	51	L1	Probe	GGCAGTCTGGGAGTGCTGAGGTTTCCCCAACA
SEQ ID NO: 123				Probe	GGCAGTCTGGGAGTGCTGCAGTTTCCCCAACA
SEQ ID NO: 124				Invader	GCTCCAACGGGTTTCCTGCACTACCAGACGTACAAATTTAACTATTAGCACTGCCACTC
SEQ ID NO: 125	O13	56	L1	Probe	GGCAGTCTGGGAGTGGTAGGAGCAGACCGCTT
SEQ ID NO: 126				Invader	CAGCCAAGCGCAGGCGGCCTCTTACGTTTTGCTGGTGTAGAGGTGGAC
	A7 Pool				
SEQ ID NO: 127	R12	45, 70	L1	Probe	CGCGCCGAGGATTCCCCTTCCCCCAGTGGC
SEQ ID NO: 128				Invader	TCCGGTGCATTATACACAAGTGTGCACACGGATATACTTGAGCGTCCTGGTACTCATGTATC
SEQ ID NO: 129				Invader	TCCGGTGCATTATACACAAGTGTGCACTAATATGCTTGAAACCCCTGGCAGTTGTGTGTC
SEQ ID NO: 130	R12	45, 70	L1	Probe	CGCGCCGAGGATTCCCCTTCCCCCAGTGGCT
SEQ ID NO: 131	R12	45, 70	L1	Probe	CGCGCCGAGGATTCCCCTTCCCCCAGTGGCTC
SEQ ID NO: 132	F3	18, 45	E6	Probe	CGCGCCGAGGGCTGGGTTCAACGGTTTCTGG
SEQ ID NO: 133				Invader	GTCCAGCTATGTTGTGGAATCGTCGTTTTTCCTTAAGGTGTCTAGGTTTTTCTC
SEQ ID NO: 134	F6	18, 39, 45	E7	Probe	CGCGCCGAGGTTTGTGTGTCCTTGGTGTGCA
SEQ ID NO: 135				Invader	TGGATGCTGTCAAGGGTGTGCCAGCAGCTGTTTCTGAAGACCCTGTCCA
SEQ ID NO: 136				Invader	GGTGGAGGCGACAGATTGTGAGAACTACAGCAGATGTTATGGACTCACTAGGAA
SEQ ID NO: 137				Invader	GGTGGAGGCGACAGATTGTGAGACTACAGCATCTGTTTTTGAGCACCTTGTCCA
SEQ ID NO: 138	T3	18,59	E6	Probe	CGCGCCGAGGGATCCTCAAAGCGAGCCAT
SEQ ID NO: 139	T3	18,59	E6	Probe	CGCGCCGAGGGGATCCTCAAAGCGAGCC
SEQ ID NO: 140			E6	Invader	ATTCTGTGCACAAATCAGGTAGCTTGTAGGGTCGTCGTGTTC
SEQ ID NO: 141			E6	Invader	TGCACAAATCAGGCAGTTTGTAAGGTCGTTGTGTAGC
SEQ ID NO: 142	R4	45, 59	E7	Probe	CGCGCCGAGGGAGCGGAACCACAGCGTCA
SEQ ID NO: 143	R4	45, 59	E6	Probe	CGCGCCGAGGCGAGCGGAACCACAGCG
SEQ ID NO: 144				Invader	GGGCCATAAATAATAATTATCCTCATGCACAACTACCGGCCCGAA
SEQ ID NO: 145				Invader	GAGGAAGAAAACGATGAACTAGATGGAGTTAATCATCATTTGCTACTAGCTAGAA
SEQ ID NO: 146	F11	18, 45	L1	Probe	CGCGCCGAGGGATTGGACAAAACGATATGTATCCAC
SEQ ID NO: 147	K5	39, 68, 70	E6	Probe	CGCGCCGAGGGGTCCGGCAATTTGTATGGCC
SEQ ID NO: 148				Probe	CGCGCCGAGGGCCATACAAATTGCCGGACC
SEQ ID NO: 149				Invader	GAATGGCGCGATTTCACAACCCTGAAGAACGC
SEQ ID NO: 150	K15	39,68,70	E6	Invader	AGATGGCGACACCAATCCGGAGAAAAATTAAGACACCTAAATAGAAAACGAAGATTTCATAAAATAGCC
SEQ ID NO: 151				Invader	AGATGGCGACACCAATCCGGCTAAGGCACCTAACAACCAAACGAAGATTACATAAAATAGCC
SEQ ID NO: 152				Invader	AGATGGCGACACCAATCCGGAACTAAGGCACCTAAATTCCAAACGAAGATTTCATAAAATAGCC
SEQ ID NO: 153				Invader	AGATGGCGACACCAATCCGGAATTAAGGCATGTTAATACAAAAAGAAGATTTCACCAAATAGCC
SEQ ID NO: 154	T16	18, 59	E7	Probe	CGCGCCGAGGGTTGCCTTTGGTCCATGCAT
SEQ ID NO: 155				Invader	CAGCCAAGCGCAGGCGTTCATTTTGTGGCTCTAAATGCAATACAATGTATTGCAATC
SEQ ID NO: 156				Invader	CAGCCAAGCGCAGGCGCTCATAATTTTGTGGTTCCAAATCTAAATCAATGTCACAAAGTC
SEQ ID NO: 157	I2	59, 70	L1	Probe	CGCGCCGAGGGCAGGTACACAGCCTATAATACA
SEQ ID NO: 158				Invader	GTCAGCCAAGCGCAGGCGTAGCCCTTCGCCCAGTGCTCTCCCATAC
SEQ ID NO: 159				Invader	GTCAGCCAAGCGCAGGCGTACAGTGCCCTGTGTCCAGTGTTCTCCAATGC
	A9 Pool				
SEQ ID NO: 160	C7	16, 35	E6	Probe	CGCGCCGAGGACGTAGAGAAACCCAGGTGT
SEQ ID NO: 161				Invader	CCAAGCGCAGGCGTAAGGCGGTCGATGTATGTCTTGTTGGAGATCATCAAGAACT
SEQ ID NO: 162				Invader	CCAAGCGCAGGCGTAAGGCAGGTCGGTGTGTGTCCTGTTGGAAACCAACT
SEQ ID NO: 163	A3 V2	16, 31, 58	L1	Probe	CGCGCCGAGGACATATTCATCTGTGCTTACAAC
SEQ ID NO: 164				Invader	TGCCTGCATGATAATAGATGTTTGTGCGTGCAT
SEQ ID NO: 165				Invader	GCCTAGAACTGCCTGCGTGATAGTATATGTTTGTTCGTGTTT
SEQ ID NO: 166				Invader	GTCTGGAACTGCCAGCGTAATAGTAAATGCTTGTGCGTGACT
SEQ ID NO: 167	PIIb	33, 52, 58		Probe	CGCGCCGAGGATGAGCAATTACGTGACAGCTC
SEQ ID NO: 168				Invader	TACTAGATATGAAACCCGAAACAACTGACCTACACTGCTC
SEQ ID NO: 169				Invader	TGTTTTAGATTTATATCCTGAACCAAGTGACCTATTCTGCTC
SEQ ID NO: 170	Z2	33, 52, 67	L1	Probe	CGCGCCGAGGGTTTACGACTGCGACG
SEQ ID NO: 171				Invader	GCCGCCACACGGACATCTGGAAAAAAATATGGAAAACT
SEQ ID NO: 172				Invader	CCGCCACACGGACATCTGTAAAAAAATATGGAAACCT
SEQ ID NO: 173	J4 v2	33, 52, 58, 67	E7	Probe	CGCGCCGAGGGCTTGTCCATCTGGCCAGTC
SEQ ID NO: 174				Invader	GCTCCAACGGGTTTCCTGCTGTCACAATGTAGTAATTGCTTGTAGCTTGTTCTT
SEQ ID NO: 175				Invader	ACAACAGGTTACAATGTAGTAATTAGCTGTGGCAGGTTGTT
SEQ ID NO: 176				Invader	GCTCCAACGGGTTTCCTGCCACACAGTAACAATTTGGTAATTGGTTGTATCTGGTTTTT
SEQ ID NO: 177	N12 v2	31, 35	L1	Probe	CGCGCCGAGGGCACGTTGCAGCCAATATGG
SEQ ID NO: 178				Invader	CAGCCAAGCGCAGGCGCCCAACAAATAGCATTATTGTGTCCCTGAC
SEQ ID NO: 179				Invader	CAGCCAAGCGCAGGCGGTTACTCCAACAAATAGCATTATTATGGCCTTGTC
SEQ ID NO: 180	Z1 v2	33, 52, 58, 67	L1	Probe	CGCGCCGAGGGCCACGGTGTACCTGCCTC
SEQ ID NO: 181				Invader	ATGTCCGTGAGGCGGCCTAGTGAGC
SEQ ID NO: 182	PIIb v2	33, 35	E7	Probe	CGCGCCGAGGATGAGCAATTGAGTGACAGCT
SEQ ID NO: 183				Invader	GGTCGTGCTCCAACGGGTTTCCTTTAGATTTGGAACTCGAGGCAACTGACCTATACTGTTC
SEQ ID NO: 184				Invader	GGTCGTGCTCCAACGGGTTTCCTTTAGATTTGCAACCTCAGGCAACTGACCTATACTGCTC
SEQ ID NO: 185	C9	16, 35	L1	Probe	CGCGCCGAGGCCAGCCCTATTAAATAAATGTCAAAC
SEQ ID NO: 186				Invader	CAGCCAAGCGCAGGCGGCCTTTAATGTATAAATCGTTTGGTACATTTTCACCAACAGTAT
SEQ ID NO: 187				Invader	CAGCCAAGCGCAGGCGCCTTAATATATAGGTCTGTAGGTACTGTTTCACCTACAGTTT
SEQ ID NO: 188	A1g v2	16, 31	E7	Probe	CGCGCCGAGGGTCCGGTTATGCTTGTCC
SEQ ID NO: 189				Invader	CAGCCAAGCGCAGGCGCTTGCAACACAAGGTTACAATATTGTAATGGGCTCTC
SEQ ID NO: 190				Invader	CAGCCAAGCGCAGGCGACTGACAACAAAAGGAAACGATATTGTAATTGGATGTC
SEQ ID NO: 191	A1g v3	16, 31	E7	Probe	CGCGCCGAGGGTCCGGTTGTGCTTGTCC
SEQ ID NO: 192				Invader	CAGCCAAGCGCAGGCGCTTGCAACACAAGGTTACAATATTGTAATGGGCTCTC
SEQ ID NO: 193				Invader	CAGCCAAGCGCAGGCGACTGACAACAAAAGGAAACGATATTGTAATTGGATGTC

Dependent claims 2 and 3 are directed to variants of the method of claim 1 and read as claims 3 and 5 of the main request, except that the dependencies have been adapted.

XI. The submissions made by the appellant concerning issues relevant to this decision, were essentially as follows:

Admission of new sets of claims into the proceedings

The new sets of claims served to adequately respond to the new objections raised by the board under Articles 123(2), 84 and 83 EPC. Hence, they could not have been filed in examination proceedings, and were filed at the earliest possible moment. The amended claims did not create a new case on appeal, but rather dealt in a straightforward manner with new objections. Therefore, they should be admitted into the proceedings.

Main request

Article 123(2) EPC – added matter

Amended claim 6 was directed to a kit and specified the first and second oligonucleotides corresponding to the A5/A6 pool (first pool), A7 pool (second pool) and A9 pool (third pool) as disclosed in Figures 7 and 10 of the application as filed. For the sake of clarity, the claim had been amended to replace the commercial name "CLEAVASE X" by the scientific term "FEN endonuclease". The amendments conformed to Article 123(2) EPC.

1st and 2nd auxiliary requests

In both requests claim 1 had been amended to specify a method in which the same pool sets included in the kit according to claim 4 were used. In the 2nd auxiliary request the claim directed to a kit had been deleted.

3rd auxiliary request

The subject-matter of the claims and the invention to which it relates fulfilled the requirements of Articles 123(2), 84 and 83 EPC.

XII. The appellant (applicant) requested that the decision under appeal be set aside and a patent be granted in accordance with the main request, or one of the 1st, 2nd or 3rd auxiliary requests, all submitted at the oral proceedings before the board on 10 May 2017.

Reasons for the Decision

Admission of new sets of claims into the proceedings – Article 13(3) RPBA

1. The sets of claims according to the present main request and 1st and 2nd auxiliary request were submitted - as 1st, 2nd and 3rd auxiliary request, respectively - in reply to the communication sent by the board in preparation of the oral proceedings. The amendments introduced into the claims are intended to overcome objections under Articles 123(2), 84 and 83 EPC raised by the board for the first time in its communication. Thus, the amended claims could not have been filed earlier. The new sets of claims do not give rise to new issues which the board cannot reasonably be

expected to deal with without adjournment of the oral proceedings, and their admission does not run contrary to procedural economy. For these reasons, the board decides to admit them into the proceedings.

2. Amended claims 1 to 3 according to the 3rd auxiliary request were filed during the oral proceedings after the discussion of the lower-ranking requests. The amendments introduced into the claims overcome the objections raised by the board under Articles 123(2), 84 and 83 EPC, and do not raise any new issues. Hence, they are admitted into the proceedings.

Main request

Article 123(2) EPC – added matter

3. Claim 6 according to the main request is directed to a kit comprising oligonucleotide detection assay components for detecting HPV sequences. Among the components of the kit are three pools of oligonucleotide sets consisting of first and second oligonucleotides. When combined with a target sequence comprising a HPV sequence, the first and second oligonucleotides form an invasive cleavage structure which can be detected in an invasive cleavage assay requiring, *inter alia*, a FEN endonuclease and a plurality of fluorescence resonance energy transfer (FRET) cassettes included in the kit (see section VIII above).

4. A kit of INVADER assay reagents for detecting HPV sequences is disclosed generally on pages 13 and 14 of the application as filed. As basis for the specific combinations of first and second oligonucleotides indicated in each row of the tables included in

claim 6, the appellant relied on Figures 7 and 10 of the application as filed. However, this basis cannot be acknowledged for each of the probe sets specified in the claim.

5. In particular, claim 6 specifies as components of a first pool a combination of oligonucleotides having "*SEQ ID NOs: 122, 123, 125*" as first oligonucleotides with oligonucleotides having "*SEQ ID NOS: 124, 126*" as second oligonucleotides (see section VIII above). While it is apparent from the first five rows of the table of Figure 10 of the application as filed (see page 12/14 of the figures) that a combination of oligonucleotides having SEQ ID NOS: 122, 123 and 124 was used in assay W18, and a combination of oligonucleotides having SEQ ID NOS: 125 and 126 in assay O13, an oligonucleotide set consisting of all these five oligonucleotides cannot be derived clearly and unambiguously from either Figure 7 or Figure 10. Nor are each of the oligonucleotide sets resulting from a combination of **any** of the first oligonucleotides (SEQ ID NOS: 122, 123 or 125) with either of the second oligonucleotides (SEQ ID NOS: 124 and 126) clearly and unambiguously derivable from Figure 7 or 10; for instance, a combination of a first oligonucleotide having SEQ ID NO: 122 with a second oligonucleotide having SEQ ID NO: 126.

6. The same applies, *mutatis mutandis*, as regards oligonucleotide sets resulting from a combination of first oligonucleotides having SEQ ID NOS: 127, 130, 131, 132, 134, 138, 139, 142, 143, 146, 147, 148, 154, 157 with second oligonucleotides having SEQ ID NOS: 128, 129, 133, 135, 136, 137, 140, 141, 144, 145, 149, 150, 151, 152, 153, 155, 156, 158, 159 (see last row of the table under "Second pool" in claim 6) or a

combination of first oligonucleotides having SEQ ID NOS: 160, 163, 167, 170, 173, 177, 180, 182, 185, 188, 191 with second oligonucleotides having SEQ ID NOS: 161, 162, 164, 165, 166, 168, 169, 171, 172, 174, 175, 176, 178, 179, 181, 183, 184, 186, 187, 189, 190, 192, 193 (see last row of the table under "Third pool" in claim 6). Neither a combination of all first and second oligonucleotides mentioned above for second or third pool, nor each possible individual combination of any first oligonucleotide with any second oligonucleotide is disclosed in the application as filed. This is evident as regards, e.g., an oligonucleotide set including a first oligonucleotide having SEQ ID NO: 146. While according to claim 6 this oligonucleotide may be combined with any of the second oligonucleotides having SEQ ID NOS: 128, 129, 133, 135, 136, 137, 140, 141, 144, 145, 149, 150, 151, 152, 153, 155, 156, 158, 159, it cannot be derived clearly and unambiguously from the application as filed which of these second oligonucleotides is used in the F11 assay disclosed in Figure 10 (see page 12/14 of the figures).

7. For these reasons, the subject-matter of claim 6 of the main request extends beyond the content of the application as filed. Hence, Article 123(2) EPC is contravened.

1st and 2nd auxiliary request

Article 123(2) EPC – added matter

8. Claim 1 of the 1st auxiliary request and that of the 2nd auxiliary request are identical (see section IX above). They are directed to a method for detecting the presence or absence of multiple HPV nucleic acids in a sample, and include the same table specifying pools of

oligonucleotide sets (referred to in claim 1 as "probe sets") as in claim 6 of the main request (see section VIII above). For the reasons given in paragraphs 5 and 6 above in connection with the main request, probe sets combining first and second oligonucleotide(s) as specified in claim 1 of the 1st and 2nd auxiliary request cannot be derived, directly and unambiguously, from the application as filed. Hence, a method as defined in claim 1 of either request, as far as it is based on the detection of an invasive cleavage structure using undisclosed oligonucleotide combinations, extends beyond the content of the application as filed.

9. As regards those combinations of first and second oligonucleotide(s) probe sets which are regarded as derivable from Figure 7 or 10 of the application as filed, the disclosure in these figures cannot be isolated from the specific embodiment of Example 5 of the application as filed, in which a FRET cassette configured to generate a detectable signal is used for detecting the formation of an invasive cleavage structure in a FRET assay. In view of the fact that the oligonucleotide probes disclosed in Figures 7 and 10 have been specifically designed for use together with a FRET cassette as illustrated in Figure 1, a person skilled in the art reading the application as filed would regard any combinations of oligonucleotides derivable from those figures as being inextricably linked to the detection of an invasive cleavage structure using such a cassette. According to the jurisprudence of the Boards of Appeal (as summarised in, e.g., decision T 1944/10 of 14 March 2014, point 3.2 of the Reasons), under these circumstances the subject-matter of amended claim 1 constitutes an "intermediate generalisation" of the disclosure in

Example 5 of the application as filed which is not allowable under Article 123(2) EPC.

10. For these reasons, the subject-matter of claim 1 of the 1st and 2nd auxiliary requests extends beyond the content of the application as filed. Hence, Article 123(2) EPC is contravened.

3rd auxiliary request

Article 123(2) EPC

11. The methods defined in amended claims 1 to 3 have a basis in the application as filed, in particular in Example 5 and the statements on page 19, lines 27 to 29 and page 20, lines 4 to 6. Thus, the amendments introduced into these claims do not offend against Article 123(2) EPC.

Article 84 EPC

12. The board shares the examining division's view that the use of cleavage means is required for successfully performing the claimed method (see page 16 of the decision under appeal). This feature is however implicit in the wording of claim 1, which specifies that the presence or absence of formation of an invasive **cleavage** structure is determined in an invasive **cleavage** assay (see step b)). It is clear from this wording that, since the cleavage structure must be cleaved, cleavage means have to be provided. Thus, contrary to the examining division, even though such means are not expressly mentioned in claim 1, the requirements of Article 84 EPC are considered to be satisfied.

Article 83 EPC – sufficiency of disclosure

13. The examining division did not raise any objection concerning Article 83 EPC. The board does not see any reason to doubt that the claimed subject-matter is disclosed in the application as filed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Thus, the requirements of Article 83 are fulfilled.

Article 111 EPC – remittal

14. Claim 1 according to the 3rd auxiliary request is limited to methods using specific combinations of particular oligonucleotides disclosed in the application as filed. In view of the amendments introduced into the claims, the question whether or not the claimed subject-matter is novel and involves an inventive step must be considered anew. Upon appellant's request, the board, exercising the discretion conferred by Article 111(1) EPC, decides to remit the case to the examining division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution upon the basis of the 3rd auxiliary request, filed at the oral proceedings before the board on 10 May 2017.

The Registrar: The Chairman:

L. Malécot-Grob P. Julià

Decision electronically authenticated